

## CLAIMS

1. A prosthetic device for use in contact with animal tissue comprising in combination:

a first body portion having a first surface portion in direct contact with said tissue; and

5 a second body portion having a second surface not in direct contact with said tissue;

said second surface having anti-microbial activity at a level greater than said first surface.

2. A prosthetic device according to claim 1 in which the second surface is in fluid contact with said tissue.

3. A prosthetic device according to claim 2 in which the second surface is in intermittent fluid contact with said tissue.

4. A prosthetic device according to claim 1 in which the first surface exhibits antimicrobial properties at a level non-toxic and non-irritating to tissue.

5. A prosthetic device according to claim 1 formed of a biocompatible material.

6. A prosthetic device according to claim 5 in which the material comprises a medical grade silicone elastomer.

7. A prosthetic device according to claim 6 in which the first body portion comprises a tubular voice prosthesis having a central channel and the second body comprises a valve, ring or cartridge mounted within said channel and in which the outer surface of the tubular voice prosthesis is the first surface and the outer surface of the valve or the inner surface of the cartridge or ring is the second surface.

8. A prosthetic device according to claim 1 in which the second surface has antimicrobial properties provided by a coating applied to said second surface or by dispersing or absorbing antimicrobial agents in the material forming said second body portion.

9. A prosthetic device according to claim 5 in which

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the antimicrobial agent is selected from the group consisting of inorganic particles of metals having antimicrobial properties and oxides, salts and halides thereof and an organic antimicrobial material.

10. A prosthetic device according to claim 5 in which the organic antimicrobial material is selected from unsaturated aliphatic acid salts thereof, halogenated hydroxy aromatic acids, esters thereof and aromatic ethers.

11. A prosthetic device according to claim 9 or 10 in which the metal, salt or oxide thereof is present in an amount from 5 to 50 phr and the organic antimicrobial material is present in an amount from 0.2 to 5% by weight.

12. A prosthetic device according to claim 10 in which the organic antimicrobial material selected from the group consisting of butyl paraben and triclosan.

13. A prosthetic device according to claim 9 in which the inorganic particles comprise silver oxide.

14. A method of increasing the life of a valve having an outside surface not in contact with tissue or a cartridge or a ring having an inside surface not in contact with tissue disposed in a channel through the body of a voice prosthesis, the outside surface of the body being in direct contact with tissue comprising the steps of:

5           providing antimicrobial activity on the outside surface of the valve or cartridge at a level that is effective to retard detrimental microbial growth; and

          disposing the valve or cartridge within said channel, said body having an outside surface that is non-irritating and/or non-toxic to said tissue.

10           15. A method according to claim 14 in which the microbial surface is provided by dispersing the antimicrobial agents in at least one of the valve, cartridge or ring.

          16. A method according to claim 14 in which microbial growth on said surface proceeds through the steps of:

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1. Depositing a biofilm;  
2. Feeding and attack by microbes of bacteria origin;

3. Feeding and attack by yeast;  
and said antimicrobial activity is provided by inhibiting or interfering with at least one of said steps.

17. A voice prosthesis for use in contact with tissue comprising in combination:

a body having a central channel and an annular wall having an inside surface and an outside surface;

5 a valve having an inside surface and an outside surface mounted to seal and intermittently open said channel; and

the outside surface of the valve not being in contact with tissue and having antimicrobial properties such that tissue in contact with said outside surface is irritated by and/or toxic to said surface.

18. A voice prosthesis according to claim 17 in which the outside surface of the body is in contact with tissue and the outside surface of the body is non-irritating to and non-toxic to said tissue.

19. A voice prosthesis according to claim 18 in which said body and said valve are formed of an elastomer.

20. A voice prosthesis according to claim 19 in which the valve is formed of a silicone elastomer containing a dispersion of or outside coating of an antimicrobial material.

21. A voice prosthesis according to claim 20 in which the antimicrobial material is selected from metal and salts and oxides thereof and organic antimicrobial materials.

22. A voice prosthesis according to claim 21 in which the material is selected from silver oxide in an amount from 6 to at least 50 phr and butyl paraben and triclosan in an amount from 0.2 to 5% by weight dispersed in the resin

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1. The first step is to identify the problem or question that needs to be addressed. This involves understanding the context and the specific requirements of the task.